OCT - 7 2003

2. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: TBD K032411

Applicant Information:

Date Prepared: August 4, 2003

Name: JS Vascular, Inc.
Address: 3337 N. Miller Rd. Ste. 105
Scottsdale, AZ 85251
Office: 480-607-1927
Fax: 480-948-0179

Contact Person: Michael A. Daniel
Phone Number: Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number: (925) 254-5187

Device Information:

Classification: Class II
Trade Name: JS Vascular Guide Wire Vise™
Common Name: Torque Device, Wire Vise
Classification Name: Catheter guidewire accessory, 74 DQX / 21 CRF 870.1330

Predicate Devices:

The JS Vascular Guide Wire Vise™ is substantially equivalent in intended use and method of operation to the following predicate devices:

Terumo Corp. Torque Device for a Guide Wire (K910969)
Boston Scientific WireClip™ Torquer (K003898)
Advanced Cardiovascular Services ACS Torque Device (K950752)
Schneider-Shiley Wire Torquer (K861606)
Advanced Cardiovascular Services Snap-on Torquer (K862409)
Procedure Products Torque Device (K922356)

Device Description:

The JS Vascular Guide Wire Vise™ is a sterile single-use wire vise/torque device consisting of a dual pin vise clamp construction. Guidance and tracking of a guidewire through the coronary or peripheral vasculature is accomplished by manual manipulation of the vise.

Intended Use:

This device is intended for use as a torque device for guidewires with a diameter of 0.014 – 0.038" to facilitate twisting and advancing the guidewire during a procedure.

Comparison to Predicate Device(s):

The JS Vascular Guide Wire Vise™ is substantially equivalent to the previously cleared Advanced Cardiovasuclar System's ACS Torque Device (K950752) and to Boston Scientific's WireClip™ Torquer (K003898) in terms of embodiment, pin vise shape, appearance and function. It has the same indications for use and makes use of the identical mechanism of action–a pin vise clamp.

Summary:

Based upon the intended use, product technical information, and performance testing results provided in this pre-market notification, the JS Vascular Guide Wire Vise™ has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 2003

JS Vascular, Inc.
c/o Mr. Michael A. Daniel
Regulatory and Clinical Affairs
3337 N. Miller Rd. Ste. 105
Scottsdale, AZ 85251

Re: K032411
Trade Name: JS Vascular Guide Wire Vise™
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: August 4, 2003
Received: August 5, 2003

Dear Mr. Daniel:

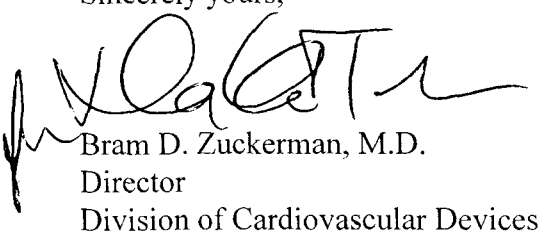
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE FORM

510(k) Number (if known): TBD

Device Name: JS Vascular Guide Wire Vise™

Indications For Use:

This device is intended for use as a torque device for guidewires with a diameter of 0.014 – 0.038" to facilitate twisting and advancing the guidewire during a procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032411